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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,907	04/20/2004	Michael T. Barrett	10031034-1	5662
22878	7590	11/30/2006	EXAMINER	
AGILENT TECHNOLOGIES INC. INTELLECTUAL PROPERTY ADMINISTRATION, M/S DU404 P.O. BOX 7599 LOVELAND, CO 80537-0599			CHO, DAN SUNG C	
			ART UNIT	PAPER NUMBER
			1634	

DATE MAILED: 11/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/828,907

Applicant(s)

BARRETT ET AL.

Examiner

Dan-Sung C. Cho

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10/27/2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 17-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>4/20/2004</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. This action is in response to the papers filed on 10/27/2006. Currently, claims 1-30 are pending. Claims 17-30 have been withdrawn as drawn to non-elected subject matter.

### ***Election/Restrictions***

2. Applicant's election with traverse of Group I, Claims 1-16 in the paper filed on 10/29/2006 is acknowledged.

3. Claims 17-30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

4. The response asserts the search and examination of an entire application can be made without serious burden in that elements of the claims of Group I are found in the remaining claims of Groups II-VIII and that the search for the claims of Group I should find any relevant prior art relating to the claims of Groups II- VIII.

5. Applicant's response have been considered but not found persuasive. It is noted that searching the invention of one group will not be coextensive with the search for other group. For example, searching for Group I (a method of using an array) will not yield art relevant to method of manufacturing an array (Group II). Additionally different inventions are classified in different class/subclass which indicate independent status in the art.

6. Therefore restriction for examination purposes as indicated is proper and is therefore made FINAL.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Bastian et al., (Bastian et al, 2001, US 2001/0029021 A1).
8. With regard to claim 1, Bastian teaches how to assess a surface-bound polynucleotide by comparing the ratios of hybridization signals of two different samples each labeled with two distinguishable labels (page 5, paragraphs 39, 46) on arrays (page 6, paragraph 59).
9. With regard to claim 2, Bastian teaches labeling with two different fluorescent labels, red and green fluorescent labels (page 8, paragraph 76).
10. With regard to claim 3, Bastian teaches a method of using non-cellular and a reference chromosome compositions in normal DNA and DNA from tumor cell lines with known aberrations (page 10, paragraph 109).
11. With regard to claim 4, Bastian teaches that a chromosomal aberration can be detected by comparing the ratios of tumor and reference fluorescence intensities (page 10, paragraph 109). For example, a chromosomal region is aberrant when the reverse labeling results in a tumor:reference fluorescent ratios are either smaller than 0.80 or greater than 1.2 (page 10, paragraph 109). The term "pre-determined ratio" refers to pre-determined ratios of particular chromosomes (e.g., any chromosomes at any ratio,

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such as 1:0, 1:1, 1:2, 2:3, 2:5, 3:5 etc. (Specification, page 23, line 26); therefore the ratios of smaller than 0.80 or greater than 1.2 Bastian teaches encompasses a pre-determined ratio.

12. With regard to claim 5, Bastian teaches pre-determined ratio may be  $<0.80$  and  $>1.2$  (page 10, paragraph 109). By teaching  $<0.8$ , Bastian teaches integer 0. By teaching  $>1.2$ , Bastian teaches integers 2 and higher. Bastian also teaches that 13/17 tumors showed no DNA copy number changes by CGH which would indicate no changes in copy number or a ratio of 1 (page 10, paragraph 114).

13. With regard to claim 6, Bastian teaches chromosomal deletion mutation can be detected by CGH (page 5, par. 46).

14. With regard to claim 7, Bastian teaches a composition not naturally occurring in a mammalian cell such as human tumor cell lines with known gain of 11p chromosomal region (page 10, par. 109). The specification discloses that a "non-naturally occurring" chromosome composition may contain chromosomes at relative levels not found in the cell and a non-cellular chromosome composition can also be thought of as a "non-naturally occurring" chromosome composition since it is never found in a cell, recombinant or otherwise. (Specification page 12, line 34 to page 13, line 3). Therefore the recited tumor cell lines can yield chromosome composition levels that is non-natural compared to normal DNA in chromosome 11p (page 10, paragraph 109).

15. With regard to claim 8, Bastian teaches a composition not naturally occurring in tumor cell lines with known gain of 11p chromosomal region compared to normal DNA (page 10, par. 109).

16. With regard to claim 9, Bastian teaches that arrays can be made with oligonucleotides (page 6 paragraph 52).
17. With regard to claim 10, Bastian teaches using human normal and tumor cells (page 10 paragraph 109).
18. With regard to claim 11, Bastian teaches a method of a CGH experiment where a first collection of chromosomal DNA from a possible tumor is labeled with a first label, while a control DNA is labeled with a second distinguishable label. The ratio of hybridization of the nucleic acids is determined (page 5, paragraph 46). The specification defines "assessing" and "assaying" include both quantitative and qualitative determinations such as detecting presence or absence of signal (page 10, line 25).
19. With regard to claim 12, Bastian teaches a method of a CGH experiment where the ratio of hybridization signals from the two labels are detected and the ratios will provide a measure of the copy number (page 5, paragraph 46).
20. With regard to claim 13, Bastian teaches a method of a CGH experiment where a DNA with known chromosomal aberration is used (page 10, paragraph 109).
21. With regard to claim 14, Bastian teaches a method of array-based CGH (aCGH) experiment (page 11, paragraph 117 and Figure 3).
22. With regard to claim 15, Bastian teaches a method of array-based CGH experiment scanning all 22 autosomal plus X and Y chromosomes of 32 primary cutaneous melanomas compared to normal human subjects (page 4, paragraph 27 and Figure 1).

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23. With regard to claim 16, Bastian teaches a method of array-based CGH experiments to determine which probes to use in order to determine the chromosomal aberrations in Spitz nevi and malignant melanoma. First, by scanning all chromosomes in an aCGH experiment (page 4, paragraph 27 and Figure 1) multiple chromosomal regions are identified as where copy numbers were changed in cutaneous melanomas (page 4, paragraph 27 and Figure 1). On the other hand chromosomal copy number changes were seen on chromosomes 7 and 11 in Spitz nevi. (page 4, paragraph 28 and Figure 2). Because of the difference in copy number aberration regions between melanocytic nevi and malignant melanoma, Bastian teaches a method of distinguishing a Spitz nevus from malignant melanoma by looking at copy numbers of 1q, 6p, 7p, or 10q and not all the chromosomes. Therefore Bastian teaches a method of identifying which probes to put on an array for CGH based on aCGH results.

24. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

### ***Double Patenting***

25. Claims 1-10 are provisionally rejected under 35 U.S.C. 103 as claiming the same invention as that of Claims 10-22 of copending Application No. 2005/0233338 A1. This is a provisional double patenting rejection since the conflicting claims have not in fact

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been patented.

26. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claims are not patentably distinct from the reference claims because the examined claims are either anticipated by or would have been obvious over, the reference claims. See e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

27. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

28. Here, Claims 10-22 of copending Application No. 2005/0233338 A1 recites a method for determining chromosome copy number change in a mammalian cell by hybridizing labeled chromosomal nucleic acids to chromosome structure region oligonucleotides and comparing the results with the same from a reference cell. Claims 10-22 of 2005/0233338 A1 also recites using oligonucleotides.



29. Claims 10-22 of 2005/0233338 A1 do not teach a using two distinguishable labels.

30. However, Bastian teaches a method of comparing the ratios of hybridization signals of two different samples each labeled with two distinguishable labels (page 5, paragraphs 39, 46) on arrays (page 6, paragraph 59) to determine chromosome aberrations. The instant claims are drawn to a broad method of aCGH and will encompass an array based chromosomal aberration detection method in Claims 10-22 of 2005/0233338 A1.

31. Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time of the invention was made to improve the method of aCGH of 2005/0233338 A1 by labeling with two distinguishable labels as taught by Bastian to simultaneously detect signals to compare. Because the instant application and Bastian are drawn to same experimental steps, namely detection of method of aCGH, one of ordinary skill in the art would have been motivated to label the two samples to compare with distinguishable labels for simultaneous signal detection (page 8, paragraph 76).

32. Claims 1, 6-10 are directed to the same invention as that of claims 1, 9-11 of commonly assigned US 7011949 B2. The issue of priority under 35 U.S.C. 102(g) and possibly 35 U.S.C. 102(f) of this single invention must be resolved.

33. Since the U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300), the assignee is required to state which entity is the prior

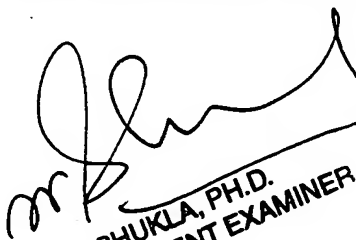
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inventor of the conflicting subject matter. A terminal disclaimer has no effect in this situation since the basis for refusing more than one patent is priority of invention under 35 U.S.C. 102(f) or (g) and not an extension of monopoly. Failure to comply with this requirement will result in a holding of abandonment of this application.

### ***Conclusion***

#### **22. No claims allowable over the art.**

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Dan-Sung C. Cho whose telephone number is (571) 272-9933. The examiner can normally be reached Monday-Friday from 7:00 a.m. to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571) 272-0735. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). The Central Fax Number for official correspondence is (571) 273-8300.



RAM R. SHUKLA, PH.D.  
SUPERVISORY PATENT EXAMINER

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